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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,864	08/10/2000	Jeffrey M. Friedman	600-1-087CIP1	6312

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,864	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *15-22 and 28-83* is/are pending in the application.

4a) Of the above claim(s) *15-22 and 28-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *59-70* is/are rejected.

7)☐ Claim(s) *71-83* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, SEQ ID NO:3 in the reply filed on 21 March 2003 is acknowledged. The traversal is on the ground(s) that there is no burden of search. Upon review of Applicant's arguments and the submission of information according to 37 CFR 1.105, the Examiner does not feel it would be an undue burden to search the human and murine sequences in the claims. Therefore, the claims will not be restricted in this manner, and this portion of the restriction requirement is withdrawn.

The requirement made in the paper mailed 28 November 2001, however, is still deemed proper. Applicant did not traverse this initial restriction requirement.

Claim Objections

Claims 71-83 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim (see claim 68). See MPEP § 608.01(n). Accordingly, the claims 71-83 not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-60, 63 and 68-70 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 59, part (d), is directed to "a nucleic acid sequence that hybridizes to any one of the nucleic acids of (a), (b), and (c)". However, the recitation of "hybridizes" without any indication of those conditions under which the hybridization is to be performed, encompasses any hybridization condition. Under unlimited conditions, all nucleic acids will stick to one another because nucleic acids are inherently sticky. Therefore the claim encompasses any and all isolated nucleic acids in existence, described or not. Applicant clearly does not describe all nucleic acids in existence and was clearly not in possession of all nucleic acids in existence, absent evidence to the contrary.

Claim 60 is directed to a nucleic acid encoding an OB protein wherein the OB polypeptide "is a mammalian OB polypeptide having the sequence of a naturally occurring mammalian OB polypeptide and having a mature protein about 145 amino acids". The instant specification provides the amino acid sequence for human and mouse OB with amino acid sequences of SEQ ID NO:2 and 4-6. The specification also contemplates proteins "displaying substantially equivalent or altered activity" (see page 14, line 18). The instant specification fails to provide a written description of other

naturally occurring mammalian OB polypeptides except for those of the human and mouse.

The recitation of "naturally occurring mammalian OB polypeptide" is directed to very specific species of protein which are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "naturally occurring mammalian OB polypeptide" cannot be predicted on the basis of the amino acid sequence of the human and mouse proteins since the disclosure of these sequences do not give guidance as to which amino acids will or will not be conserved in the other naturally occurring mammalian OB proteins. The claims are directed to nucleic acids encoding a species of protein, the structure of which cannot be determined or predicted from the sequences of the human and mouse proteins and the specification does not evidence isolation or conception of the structure of other "naturally occurring mammalian OB" polypeptides, therefore, the specification does not provide an adequate written description of such, and thus the claimed invention, to the extent that it reads upon other OB polypeptides from other species was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath In. v. Mahurkar, 19 USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for the purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117.) To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is a functional recitation of modulating body weight. There is no structure recited, except that the protein should be about 145 amino acids long. The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

With the exception of very particular amino acid sequences which are disclosed in the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of protein expression. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See Fiers v. Revel,

25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF=s were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) The instant claims are directed to a structure, which could be made, but for which, there is no written description. As in Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class because the specification provided only the bovine sequence. In the instant situation, the specification only provides the amino acid sequence structure for human and mouse of SEQ ID NO:2 and 4-6, but fails to provide a description of the broad class of naturally occurring mammalian OB polypeptides, regardless of whether they could be made or isolated.

Claim 63 is rejected for new matter for the recitation of "83 percent or greater amino acid sequence identity". This percentage could not be found in the instant specification as originally filed, and is therefore, considered new matter. Applicant is invited to point out the basis for this claim limitation.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 59, part (e), is directed to "a nucleic acid sequence that encodes an expression product of an amino acid sequence encoded by any of the foregoing nucleic acid sequences". Part (d) of this claim is directed to nucleic acid [sequences] which hybridize to coding sequences. Therefore, the sequences of part (d) are not coding, and part (e) of the claim is clearly not enabled for encoding when it refers to part (d). Secondly, part (e) of this claim recites "an expression product of an amino acid sequence". No reading frame has been indicated in the previous parts of the claim, therefore, there could be multiple expression products encompassed by the recited nucleic acids. The instant specification only describes and enables the ob molecules encoded by these nucleic acid molecules, and no other potential expression products, as encompassed by the language of part (e) of the claim. The specification fails to teach how to make and use other expression products which could be encoded for by the recited nucleic acid molecules, absent evidence to the contrary.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 recites the limitation "a nucleic acid sequence" in parts (d) and (e). There is insufficient antecedent basis for this limitation in the claim because the preamble refers to "isolated nucleic acid molecule". Additionally, Applicant should be claiming the DNA molecule and not the "sequence". The sequence is merely a written representation of a characteristic of the DNA molecule, and the sequence is not the molecule.

Claims 60-67 include the recitations of "having one or more polymers attached thereto" and "optionally in a pharmaceutical carrier". However, it is not clear if these recitations are directed at the nucleic acid molecules or at the polypeptide. If they are directed at the polypeptide, they are confusing. For example, what limitation is placed on the nucleic acid if the encoded polyeptide is "optionally in a pharmaceutical carrier"? This limitation is confusing and clearly does not convey to the nucleic acid if it is a limitation on the polypeptide. Likewise, it is not clear if the polymers are attached to the nucleic acid or the polypeptide. If the nucleic acid is to encode a polypeptide that has polymers attached, then the claims will only be enabled for those polymers which could be encoded by the nucleic acid (i.e. polyaminoacids). It is noted that the specification discloses chemical modification of the polypeptide for the attachment of polymers. If this limitation is one to be placed on the polypeptide, upon amendment, a new ground of rejection may be necessary because the claims would only be enabled for those polymers that the nucleic acid could encode.

Claims 64-67 recite "wherein said OB polypeptide encoded by said isolated nucleic acid is an OB polypeptide variant" and then recite a host of amino acid positions

to be changed. There is no antecedent basis for the variant. There is no structure recited for the OB polypeptide, and therefore, there is no antecedent basis for the amino acid positions which are to be modified in the variant. The claims are indefinite because it is not clear what structures are intended.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,935,801 and claims 1-21 of U.S. Patent No. 6,309,853.

U.S. Pat. No. 5,935,801 and 6,309,853 claim nucleic acids encoding OB polypeptides, which are the same as the OB polypeptides recited in the instant claims. However, some of the instant claims do include a recitation of "having one or more polymers attached thereto" and "optionally in a pharmaceutical carrier". As pointed out before, it is not clear if these limitations are to be placed on the protein or the nucleic

acid. Regardless, the proteins of '801 and '853 use comprising language and therefore, conceivably include additional amino acids, such as polyamino acids. Therefore, the instant claims are not identical to those of '801, but they are encompassed by the claims of '801.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
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